

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

|   |   |                   |
|---|---|-------------------|
| In re Patent Application of             | ) | MAIL STOP PCT     |
| Didier HOARAU et al.                    | ) | Group Art Unit:   |
| Application No.:                        | ) | Examiner:         |
| Filed:                                  | ) | Confirmation No.: |
| For: STEALTH LIPID NANOCAPSULES,        | ) |                   |
| METHODS FOR THE PREPARATION             | ) |                   |
| THEREOF, AND USE THEREOF AS A           | ) |                   |
| CARRIER FOR ACTIVE PRINCIPLE(S)         | ) |                   |
| National Stage of                       | ) |                   |
| International Appln. No. PCT/IB03/03213 | ) |                   |
| Filed: June 11, 2003                    | ) |                   |
| Earliest Priority Date: June 11, 2002   | ) |                   |

#2

**FIRST INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, the accompanying information is being submitted in accordance with 37 C.F.R. §§ 1.97 and 1.98. It is requested that the Examiner consider the documents listed on the accompanying Form PTO-1449, as well as the enclosed copies of the International Search Report and International Preliminary Examination Report issued in connection with International Appln. No. PCT/IB/03213, of which the present application is the U.S. national stage.

Pursuant to 37 C.F.R. § 1.98, a copy of each of the cited documents is enclosed. However, copies of the listed U.S. patents and U.S. patent application are not enclosed since it is no longer required according to the July 11, 2003 waiver of the requirements for copies of cited U.S. patents and U.S. patent application publications in national patent applications filed after June 30, 2003 and international applications entering the national stage under 35 U.S.C. § 371 after June 30, 2003.

Two of the cited documents are not in English. With respect to these non-English documents, the following additional remarks are offered:

WO 01/64328 is in French. This document is cited in the English-language International Search Report as a category "A", general state of the art, reference. Applicants are providing an English abstract/patent family search of this document; English-language

counterpart, Heurtault et al. U.S. Published Appln. No. 2003/0152635, serves as an English translation.

The Larpent reference entitled "Tensioactifs" is in the French language. No English translation is available to applicants or their representatives. This document is referred to on page 6, lines 25-26, of the specification. This document is a general review of surfactants. Point 1 deals with chemical structures and different classes of surfactants. Point 2 deals with the properties of surfactants. Point 3 deals with the uses and choice criteria of surfactants. Finally, point 4 is a guide for a quick selection of surfactants.

WO 03/103822 is the published version of the international phase of this § 371 application and is cited merely to complete the record. It is not prior art herein.

Finally, the reference by Didier Hoarau et al., authored by the present inventors and coworkers, was published after the filing date of International Appln. No. PCT/IB03/03213 and is therefore not prior art. It is cited merely to complete the record.

This Statement, Form PTO-1449 and enclosures are being submitted within three (3) months of the filing or entry of the national stage of this application or before the first Office Action on the merits, whichever is later. Since these documents are being filed within the time period set forth in 37 C.F.R. § 1.97(b), no fee or statement is required.

It is respectfully request that the Examiner consider this statement and accompanying papers and documents and return an Examiner-initialed copy of the Form PTO-1449 to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date March 10, 2005

By: Mary Katherine Baumeister  
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U.S. National Stage of:

Int'l. Appln. No. PCT/IB03/03213

Inventor: Didier HOARAU et al.

Int'l. Filing Date: June 11, 2003

Attorney Docket No.: 017753-201

FIRST IDS Filed: March 10, 2005

(17 Documents Attached)

# **FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

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of

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Complete if Known

Application Number

Filing Date

First Named Inventor

Didier HOARAU et al.

Examiner Name

Attorney Docket Number

017753-201

## **U.S. PATENT DOCUMENTS**

| Examiner Initials | Document Number | Kind Code (if known) | Name of Patentee or Applicant of Cited Document | Issue/Publication Date (MM-DD-YYYY) |
|-------------------|-----------------|----------------------|---|-------------------------------------|
|                   | 2003/0152635    | A1                   | HEURTAULT et al.                                | 08-14-2003                          |
|                   | 5,811,119       |                      | MEHTA et al.                                    | 09-22-1998                          |
|                   | 5,527,528       |                      | ALLEN et al.                                    | 06-18-1996                          |

## **FOREIGN PATENT DOCUMENTS**

| Examiner Initials | Document Number | Kind Code (if known) | Country | Date of Publication (MM-DD-YYYY) | STATUS         |                     |                    |               |      |          |               |
|-------------------|-----------------|----------------------|---------|----------------------------------|----------------|---------------------|--------------------|---------------|------|----------|---------------|
|                   |                 |                      |         |                                  | Translation    | Partial Translation | Eng. Lang. Summary | Search Report | IPER | Abstract | Cited in Spec |
|                   | 02/00194        | A2                   | WO      | 01-03-2002                       |                |                     |                    |               |      |          |               |
|                   | 01/64328        | A1                   | WO      | 09-07-2001                       | X <sup>1</sup> |                     |                    |               |      | X        |               |
|                   | 03/103822       | A2                   | WO      | 12-18-2003                       |                |                     |                    |               |      |          |               |
|                   | 99/30620        | A1                   | WO      | 06-24-1999                       |                |                     |                    |               |      |          |               |
|                   | 98/51284        | A1                   | WO      | 11-19-1998                       |                |                     |                    |               |      |          |               |

## **NON-PATENT LITERATURE DOCUMENTS**

| Examiner Initials | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. |
|-------------------|---|
|                   | MORI et al., FEDERATION OF EUROPEAN BIOCHEMICAL SOCIETIES, VOL. 284, NO. 2, ELSEVIER SCIENCE PUBLISHERS B.V., 1991, PP 263-266, Amsterdam, The Netherlands.   |
|                   | ALLEN, TIPS, VOL. 15, ELSEVIER SCIENCE LTD., JULY 1994, PP 215-220, Amsterdam, The Netherlands.   |
|                   | ALLEN et al., BIOCHIMICA ET BIOPHYSICA ACTA, VOL. 1066, ELSEVIER SCIENCE PUBLISHERS B.V., 1991, PP 29-36, Amsterdam, The Netherlands.   |
|                   | GABIZON et al., PROC. NATL. ACAD. SCI. USA, VOL. 85, 1988, PP 6949-6953, National Academy of Sciences, Washington, D.C.   |
|                   | LASIC, TIBTECH, VOL. 16, ELSEVIER SCIENCE LTD., 1998, PP 307-321, Amsterdam, The Netherlands.   |
|                   | LARPENT, "Tensioactifs", in <i>Techniques de l'Ingenieur. Constantes Physico-Chimiques</i> , ed. Francoise Hurtaud, published by Techniques de l'Ingenieur, Paris, France, pp. KK 342-1 to K-342-14 (1991).   |
|                   | STOLNIK et al., JOURNAL OF DRUG TARGETING, VOL. 9, OVERSEAS PUBLISHERS ASSOCIATION N.V., 2001, PP 361-378, Taylor & Francis Ltd., Abingdon UK.  |
|                   | CAHOUE et al., INTERNATIONAL JOURNAL OF PHARMACEUTICS, VOL. 242, ELSEVIER SCIENCE B.V., 2002, PP 367-371, Amsterdam, The Netherlands.   |
|                   | MOSQUEIRA et al., PHARMACEUTICAL RESEARCH, VOL. 18, NO. 10, PLENUM PUBLISHING CORPORATION, OCTOBER 2001, PP 1411-1419, New York, New York.  |
|                   | LIU et al., BIOCHIMICA ET BIOPHYSICA ACTA, VOL. 1240, ELSEVIER SCIENCE B.V., 1995, PP 277-284, Amsterdam, The Netherlands.  |
|                   | VERRECCHIA et al., JOURNAL OF CONTROLLED RELEASE, VOL. 36, ELSEVIER SCIENCE B.V., 1995, PP 49-61, Amsterdam, The Netherlands.   |
|                   | Didier HOARAU et al., "Novel Long-Circulating Lipid Nanocapsules", <i>Pharmaceutical Research</i> , Vol. 21, No. 10, pages 1783-1789, October 2004, Springer Science + Business Media, Inc., Berlin, Germany.   |

<sup>1</sup>See English-language counterpart, Heurtault et al. U.S. Application Publication Number 2003/0152635.

|                    |                 |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.